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3000 7590 09/12/20008 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD.			EXAM	EXAMINER	
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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patents@crbcp.com

## Application No. Applicant(s) 10/536.674 MULLER ET AL. Office Action Summary Examiner Art Unit ALEX NOGUEROLA 1795 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 5/27/2005 (preliminary amendment). 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 14-27 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 14-27 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10)⊠ The drawing(s) filed on 27 May 2005 is/are: a)⊠ accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

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#### DETAILED ACTION

#### Election/Restrictions

 The current examiner has withdrawn the restriction requirement made by the previous examiner.

### Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 14-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:
- a) Claim 14 recites the limitation "second electrode layer" in line 7. There is insufficient antecedent basis for this limitation in the claim.
- b) Claim 14 recites the limitation "second passivation layer" in line 8. There is insufficient antecedent basis for this limitation in the claim (where is the first passivation layer?).
  - c) Claim 27 it is not clear what "laver structures" refers to.
- 4. Note that dependent claims will have the deficiencies of base and intervening claims.

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#### Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

 Claims 14 and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Medoro WO 00/69565 A1 ("Medoro").

Addressing claims 14, Medoro discloses a fluidic microsystem comprising: at least one channel (L – Figure 1) through which a particle suspension (BIO) can flow (Figure 1); and

first (M1 (electrodes L1-L12)) and second (M2) electrode devices which are arranged on first and second channel walls for generating electrical alternating-voltage fields in the channel (Figures 1 and 2); wherein

the first electrode device is adapted for field shaping in the at least one channel and comprises at least one first structure element (Figures 1 and 2 and page 13. last paragraph - page 19, second line); and

the second electrode device comprises an area-like second electrode layer

(Figures 1 and 2), wherein

an effective electrode surface of the at least one first structure element is smaller than the closed second electrode surface (Figures 1 and 2); and

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the second passivation layer (R2) wherein the second passivation layer is a closed layer completely covering the second electrode layer (Figures 1 and 2 and third full paragraph on page 13).

Addressing claim 17, for the additional limitations of this claim see Figures 1 and 2 in Medoro and note first passivation layer R1.

### Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.

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Resolving the level of ordinary skill in the pertinent art.

Considering objective evidence present in the application indicating obviousness or nonohyiousness.

- 9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 10. Claims 14-17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles US 6,685,812 B2 ("Miles") in view of Schnelle et al. ("Adhesion-Inhibited Surfaces. Coated and Uncoated Interdigitated Electrode arrays in the Micrometer and submicrometer Range," Langmuir 1996, 12, 801-809) ("Schnelle"), Krulevitch et al. US 6,352,838 B1 ("Krulevitch"), and Fuhr et al. US 6,113,768 ("Fuhr").

Addressing claim 14, Miles discloses a fluidic microsystem comprising: at least one channel (11) through which a particle suspension can flow (30); and first (any one of electrodes 12-20) and second (23) electrode devices which are arranged on first and second channel walls for generating electrical alternating-voltage fields in the channel (Figures 1-4 and col. 03:36-47); wherein

the first electrode device is adapted for field shaping in the

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at least one channel and comprises at least one first structure element (col. 03:48-65); and the second electrode device comprises an area-like second electrode layer (Figures 2-4 and col. 03:42-47), wherein

an effective electrode surface of the at least one first structure element is smaller than the closed second electrode surface (Figures 2-4).

Miles, though, does not mention providing a closed second electrode surface comprising a second passivation layer wherein the second passivation layer is a closed layer completely covering the second electrode layer.

Schnelle, Krulevitch, and Fuhr disclose coating a passivation layer onto electrode arrays in a fluidic microsystem wherein the electrode arrays are for generating electrical alternating-voltage fields in the channel to act on particles therein. See in Schenlle the abstract and Figure 3, in Krulevitch the abstract and col. 03:37-41, and in Fuhr the abstract and Figures 1, 2, and 5.

It would have been obvious to one with ordinary skill in the art at the time of the invention to coat the electrodes with a passivation layer as taught by Schnelle, Krulevitch, and Fuhr in the invention of Miles because as taught by Schnelle then the electrodes will protected for many days from cell adhesion and deposition of artificial particles, which would otherwise reduce the lifetime and accuracy of the electrodes, similarly, as taught by Krulevitch this will reduce or essentially prevent undesirable particles and/or molecules from sticking to the electrode outer surface during operation, and as taught by Fuhr in addition to preventing adhesion of particles to the electrodes the passivation layer allows higher voltages to be applied to the electrodes, and "...

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balance[s] out the traveling electrical field suitably in the near-surface liquid space and on the other [hand] prevent[s] electrolytic processes so that the electrical used in physiological solutions of high conductivity."

See in Schnelle the abstract, the first paragraph of *I. Introduction*, and *IV. Conclusions*; in Krulevitch see col. 03:37-53, and in Fuhr Figure 5, col. 02:42-54 and col. 03:30-49.

Addressing claims 15 and 16, for the additional limitations of these claims see Figure 1 in Miles.

Addressing claim 17, as for first layer structures see Figures 1 and 2 in Miles. As for a closed first passivation layer it would have been obvious to one with ordinary skill in the art at the time of the invention to also provide a closed passivation layer on the first electrode as done for the second electrode for the same reasons as set forth in the rejection of underlying claim 14, namely, to prevent undesirable adhesion of particles onto the electrodes, to balance out a traveling wave (if traveling wave dielectrophoresis is performed), to prevent electrolytic process, and to allow higher voltages to be applied to the electrodes.

Addressing claim 24, for the additional limitations of this claim see in Krulevitch col. 03:37-53, especially lines 46-53.

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11. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles

US 6,685,812 B2 ("Miles") in view of Schnelle et al. ("Adhesion-Inhibited Surfaces. Coated and Uncoated Interdigitated Electrode arrays in the Micrometer and submicrometer Range," Langmuir 1996, 12, 801-809) ("Schnelle"), Krulevitch et al. US 6,352,838 B1 ("Krulevitch"), and Fuhr et al. US 6,113,768 ("Fuhr") as applied to claims 14-17, 24 above, and further in view of Miles et al. (US 6,787,018 B1) ("Miles II").

Miles as modified by Schnelle, Krulevitch, and Fuhr does not disclose providing a third electrode device for generating electrical direct-voltage fields or direct-voltage pulses in the at least one channel or in a transverse channel branching off from the at least one channel.

Miles II discloses a fluidic microsystem comprising: at least one channel (11) through which a particle suspension can flow (16); and first (any one of electrodes 18 or 20) and second (11) electrode devices (the other of electrodes 18 or 20) which are arranged on a channel wall for generating electrical alternating-voltage fields in the channel (Figures 1 and col. 02:60 – col. 03:11); wherein

the first electrode device is adapted for field shaping in the at least one channel and comprises at least one first structure element (col. 03:48-65); and the second electrode device comprises an area-like second electrode layer

(Figure 2). Miles II further discloses providing an additional electrode device for generating electrical direct-voltage fields or direct-voltage pulses in the at least one channel. See Figure 1 and col. 02:60 – col. 03:03. It would have been obvious to one

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with ordinary skill in the art at the time of the invention to provide a third electrode device as taught by Miles II in the invention of Miles as modified by Schnelle, Krulevitch, and Fuhr because as taught by Miles II "[e]lectrokinetic/electroosmotic flow is also useful in these devices (microfluidic systems] because it obviates the need for micropumps and microvalves" and "... [p]articles swept down the channel electrokinetically are trapped within the field established by the interdigitated electrodes. Thus, the apparatus can be used to concentrate the sample prior to testing due to the combined use of dielectrophoresis and elecrokinetic/electroosmotic flow." See col. 01:30-42 and col. 03:12-23.

### Allowable Subject Matter

- 12. Claims 18-23, 26, and 27 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
- 13. The following is a statement of reasons for the indication of allowable subject matter:
  - a) Claim 18: the combination of limitations requires both that "the second passivation layer comprises at least one second structure element for field shaping in the at least one channel, said at least one second structure element being formed by second layer structures in the second passivation layer" and that

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the "an effective electrode surface of the at least one first structure element is smaller than the closed second electrode surface." In the rejection of claim 14 based on Miles as modified by Schnelle, Krulevitch, and Fuhr electrode 23 in Miles is construed as the claimed second electrode device. This electrode spans the entire length of the substrate on which it is located. See col. 03:36-47. So it would not have been obvious to provide a second structure element for field shaping (e.g., another electrode) in the second passivation layer which covers the second electrode. The first electrode device in Miles (electrodes 12-20), which has multiple electrodes (structures elements for field shaping) can not be construed as the second electrodes device instead of electrode 23 because as noted above claim 18 also requires "an effective electrode surface of the at least one first structure element is smaller than the closed second electrode surface."

Similarly, in Medoro the second electrode deice spans the length and width of its supporting substrate. See Figures 1 and 2. Any additional electrodes for field shaping would be provided on the opposing substrate as part of the electrode array on that substrate.

b) Claims 19-22 depend directly or indirectly from allowable claim 18.

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c) Claim 23 requires the "at least one of the first passivation layer and the second passivation layer [to] comprise(s) several layers." In the microsystem of Miles as modified by Schnelle, Krulevitch, and Fuhr the first and second passivation layer comprise only one layer each. Similarly, in Medoro the first and second passivation layer

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comprise only one layer each.

d) Claim 26 requires that "... an external electrode device is provided for generating electrical direct-voltage fields or direct-voltage pulses in the at least one channel or in a transverse channel branching off from the at least one channel." In the microsystem of Miles as modified by Schnelle, Krulevitch, and Fuhr there is an external electrode device in a channel branching off from the at least one channel (Figure 5 in Miles); however, the external electrode device is for dielectrophoresis, that is for generating an AC signal. See col. 04:07-12 and col. 02:50-55.

e) Claim 27 requires that the fluidic microsystem according to claim 14 be used for field shaping, "... wherein a geometric shape of electrical fields in the channel is determined by a geometric shape of layer structures in passivation layers in which there is a modified field transconductance." In the microsystem of Miles as modified by Schnelle, Krulevitch, and Fuhr the electrodes are substantially rectangular, for example, the large-area second electrode device in Miles or the narrow linear band electrode of the first

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electrode device or the narrow linear band electrode projections in Figures 3B and 6-9 in Krulevitch and Figures 1 and 3 in Fuhr. Müller ("A 3-D microelectrode system for handling and caging single cells and particles," Biosensors & Bioelectronics 14 (1999) 247-256) discloses a microfluidic microsystem comprising a channel having electrodes with different geometric shapes for field shaping. See the abstract and Figure 4. However, the electrodes on the opposing channel surfaces are mirror images of each other and so if used in the microsystem of Miles they would not provide an effective electrode surface of the at least one first structure element that is smaller than the closed second electrode surface as required by claim 14.

f) the International Search Report for International Application No. PCT/EP03/13319

lists US 6,387,707 B1 as an "X" reference against claims 1-13; US 2002/166766A1 as an "X" reference against claims 1, 2, 4, 6-10, 13; Schnelle et al., Langmuir vol. 12, 1996, pages 801-809 as an "X" reference against claim 13; and Reimer et al. Sensors and Actuators A, vol. 46, no. 1-3, January 1995, pages 66-70 as an "X" reference against claim 13. These references were also used in rejections in the in International Preliminary Examination Report for International application No. PCT/EP03/13319.

Claims 1-13 in the instant application were canceled by preliminary amendment and replaced with claims 14-27 of which only claim 14 is an independent claim.

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US 6,387,707 B1 does not disclose a second passivation layer completely covering the second electrode as required by claim 14. It relies on "stringent conditions of cleanliness" to avoid non-specific particle adsorption to the electrode surface.

See col. 09:52-55.

US 2002/166766A1 does not disclose a second passivation layer completely covering the second electrode as required by claim 14. The opposing electrodes are uncovered. See paragraph [0118].

In Schnelle the first and second electrode devices are arranged on the same channel wall and have the effective electrode surface of the at least one first structure element is the same as the closed second surface (see "II. Material and Methods – Microelectrode Fabrication" on page 801-802 and Figures 1-3 and 5), unlike the fluidic microsystem of claim 14.

In Reimer et al. the electrode devices are all on the same channel wall. See Figure 1.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/

Primary Examiner, Art Unit 1795